JUN 1 8 2014

K130581
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS [21 CFR 807.92(c)]

Date Summary Was Prepared: June 13, 2014

Submitter:

Official Contact Person: Ronald J. Amen, Ph.D
On Behalf of: TurkuazSaglikHizmetleriMedikalTemizlik Kimyasal Urunleri San.Ve Tic. Ltd. Sti.
SaadetdereMah. 67 Sok No: 3
Esenyurt
ISTANBUL TR-34513
Turkey
90-212-4286848
Contacts: Nurhan Irmak

Device [807.92(a)(2)]:

Trade or Proprietary Name:	KONIX® Sterile Gel
Common or Usual Name:	Sterile Ultrasound Gel
Classification Name: (UCD)	Transducer, Ultrasonic, Diagnostic
Product Code:	MUI
Regulation Number:	21 CFR 892.1570
Device Class	Class II
Classification Panel	Radiology

By Prescription Only

Predicate Device [80792(a)(3)]:

KONIX® Sterile Gel is substantially equivalent to:

Sterile Aquasonic® 100 Ultrasound Gel (Parker Laboratories)

Description of the Device [807.92(a)(4)]:

Konix® Sterile Gel is an *in vivo* biocompatible sterile couplant intended for use as a scanning gel in surgical procedures, biopsies and similar sterile applications. It is used to couple sound waves between the patient and medical imaging electronic transducers during intraoperative and intracavitary medical diagnostic ultrasound imaging procedures such as transcutaneous ultrasound image guided biopsy and aspiration, doppler examinations of organ and tissue intraoperative ultrasound imaging, intra-cavity ultrasound imaging, and gel infusion sonography.

Major characteristics include:

- No toxic effects; produced as a completely harmless material
- Hypoallergenic; non-irritating; no cytotoxicity
- Water soluble, non-staining and easily cleanable
- Does not contain any lipid components
- Free from formaldehyde and salt
- Odorless
- Gamma radiated to assure sterility
- Will not damage the probe
- Does not contain air bubbles
- pH = 7

Packaging and Labeling

Konix® Sterile Gel is sold in 20 mL (0.67 oz), single-use sachets. The sachets are composed of polyester (12 micron), aluminum foil (7 micron), and polyethylene (80 micron), and are terminally sterilized using gamma irradiation. The sachets are 60 mm wide and 130 mm long. The labeling information on the package complies with the FDA requirements. The shelf package has been examined and found have maintained integrity and sterility over a three year period.

Indications for Use [807.92(a)(6)

As stated on Label: Contact medium for ultrasonic and electrical transmission gel.

Konix® Sterile Gel is sterilized by gamma irradiation and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility and *in vivo* biocompatibility are required. It can be used on the skin where the risk for infections is especially high, especially with open tissue Doppler applications; and can be used for cystoscopic and vaginal Doppler and ultrasound examinations.

Konix® Serile Gel can be used on the skin or in open tissue where there is a risk for infections, such as in open tissue Doppler applications. It can be used during surgery; for cystoscopic and vaginal ultrasound and Doppler examinations; for cardiac surgery and ultrasound procedures; and as a lubricant in biopsy applications.

Technological Characteristics [807.92(a)(6)]

Both the predicate device (Parker Laboratories' Sterile Aquasonic® 100 Ultrasonic Gel) and Konix® Sterile Gel have the same technological characteristics. They are both polymer-based gels that contain similar ingredients that allow their use in ultrasonic applications. Independent testing of Konix® Sterile Gel indicated that "the acoustic properties of this gel are very similar to those of other coupling gels commonly employed."

PHYSICAL AND CHEMICAL PROPERTIES	Very high clarity
	Hypoallergenic, non-cytotoxic, and non-sensitizing
	Sterile
	pH = 6.5 ± 0.75
	Density(g/cm3)=0.983
	Very clear screen image with high viscosity and vacuum process. No rapid melting from high-viscosity gel. Viscosity: 100,000-200,000 cp
	Boiling Point> 200°F
	Water soluble high molecular weightpolymer

Substantial Equivalence [807.92(b)(1)]

Turkuaz Konix® Sterile Gel has been determined to be substantially equivalent to Parker Laboratories' Sterile Aquasonic® 100 Ultrasound Gel, a marketed device. The sterility, intended use, active ingredients and other components, and packaging, are substantially equivalent to the predicate device.

FEATURES	TURKUAZ KONIX® STERILE GEL	PARKER LABS STERILE AQUASONIC® 100 ULTRASOUND GEL
• Sterile formula	√	√
• Aqueous solution will not stain clothing or damage transducers	√	√
• Convenient single- use foil pouches	√	√
• Suitable for broad range of ultrasound frequencies	√	√
• Viscous ultrasound transmission gel	√	√
• Hypoallergenic	√	√
• Bacteriostatic for increased hygiene	√	√
• Non-sensitizing and non-irritating for patient comfort	√	√

• Formula does not	√	√
• Not a spermicide	√	√
• Clear, Pale Yellow Color	√	√
• 20 mL/20 gm	√	√
• Ingredients: Polymer, Humectants, Preservatives, Water	√	√
• pH Range	6.5 - 7.5	6.5 - 6.95
• Density	0.983 g/cm^3	1.03 g/cm3
• Acoustic Impedance	1.45 (10^5gm/cm^2)	1.60 (10^5gm/cm^2)

Production

Konix® Sterile Gel is produced in a closed-loop system so that contamination is eliminated. The carbomer and monopropylene glycol are added to water in a mixer. There is an in-process quality control that confirms the correct percentage of ingredients. The preservatives are then added, and the pH is adjusted. A final analysis is conducted on the mixture, and then the product is filled. The product is produced in a 100,000 class clean room with Hepa filters. The process includes a vacuum process so that bubbles cannot form. After production, the sterile gel is gamma irradiated according to accepted standards, to assure sterility. The product has a three year shelf-life.

Ingredients

KONIX® STERILE GEL

INGREDIENTS	COMMON CHEMICAL NAME	CAS NUMBER	QUANTITY (w/v %)
Carbomer	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	9003-01-004	0.3-1.0
Triethanolamin	Triethanolamin	102-71-6	0.3-1.0
MonoPropylene Glycol	MonoPropylene Glycol	57-55-8	0.5-2.0
5-chloro-2-methyl-4-isothiazolin-3-one 2-methyl-4-isothiazolin-3-one	Methylchloroisothiazolinone (and) Methylisothiazolinone	26172-55-4 2682-20-4	0.05-0.15
Deionized water	Deionized water	-	Q.S 100

Carbomer, triethanolamin, and monopropylene glycol constitute the ingredients that form the gel. These are common ingredients used for this purpose. Methyl-chloroisothiazolinone (5-chloro-2-methyl-4-isothiazolin-3-one) is a preservative with antibacterial and antifungal effects within the group of isothiazolinones. It is effective against gram-positive and gram-negative bacteria, yeast, and fungi. Methylisothiazolinone, is a powerful general biocide and preservative within the group of isothiazolinones, often used in personal care products.

Release Specifications

Item	Specification and Range
pH	6.50-7.50
Density	0.683-1.283 (g/cm^3)
Carbomer	0.3-1.0 (w/v %)
Triethanolamin	0.3-1.0 (w/v %)
MonoPropyleneGlyco	0.5-2.0 (w/v %)
5-chloro-2-methyl-4-isothiazolin-3-one & 2-methyl-4-isothiazolin-3-one	0.05-0.15 (w/v %)
Odor	Odorless
Clarity	Clear
Microbes	Zero CFU/Gm (Sterile)

Performance Test

The results of the acoustic tests indicated that "no effect of attenuation or impedance mismatch with the gels could be observed in imaging of the test objects in numerous real time sweeps." The report stated that the acoustic impedance of 1.49 kg/m^2s for the Konix® gel is close to the reported mean human dermis of 1.6 kg/m^2s, and should minimize reflection loses and generation of reverberant echoes when gel layers of at least 1/4 wavelength are employed. The speed of sound of 1516 m/s is very close to the 1518 m/s reported for skin, and this should minimize refract errors for oblique incidence into skin after passage through finite thicknesses of gel and keep elevation focus for RTV lense material as designed. In conclusion, the researchers stated that the "acoustic properties of this gel are very similar to those of other coupling gels commonly employed.

Sterility and Shelf-Life

Independent testing confirmed that Konix® Sterile Gel is free of microbes following sterilization radiation. No aerobic mesophilic bacteria were present in either tryptone soy broth or fluid thioglycollate medium after 14 days of storage at 30°C.

Storage stability testing at 22° and 40°C indicated that Konix® Sterile Gel is stable for three years at ambient temperatures when pH, density, viscosity, and appearance were measured. Additionally, examination of packages over a three year period showed that there was no microbial growth, thus confirming long-term package integrity and sterility.

Additional Tests

In vitro cytotoxicity, *in vivo* sensitization, irritation tests, and mouse systemic toxicity tests were conducted with the Konix® Sterile Gel according to standard protocols. All tests proved negative for cytotoxicity, sensitization, irritation, and systemic toxicity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2014

Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal
Urunleri San. Ve Tic. Ltd. Sti.
% Mr. Michael Scott
President
ST&T Consultants, Inc.
2237 Chestnut Street
SAN FRANCISCO CA 94123

Re: K130581
Trade/Device Name: Konix® Sterile Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: May 13, 2014
Received: May 23, 2014

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

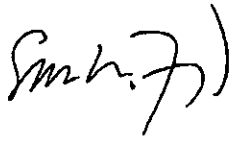
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130581

Device Name
Konix Sterile Gel

Indications for Use *(Describe)*
As stated on Label: Contact medium for ultrasonic and electrical transmission gel.
Konix® Sterile Gel is sterilized by gamma irradiation and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in combination with a transducer cover, where sterility and in vivo biocompatibility are required. It can be used on the skin where the risk for infections is especially high, especially with open tissue Doppler applications; and can be used for cystoscopic and vaginal Doppler and ultrasound examinations.
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cystoscopic and vaginal ultrasound and Doppler examinations; for cardiac surgery and ultrasound procedures; and as a lubricant in biopsy applications

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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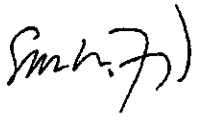
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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